Contents: Using Controlled Substances in Research

Effective Date: **September 2002**
Point of Contact: Clinical Research Center (CRC) Manager

Section	Overview of Content (see section for full process)
Introduction	
1. Obtaining Authorization	✍ Identify the controlled substance. ✍ Determine if controlled substance is Schedule I or Schedule II - V. ✍ Verify and document that controlled substance is on the DEA license. ✍ Obtain approval for use of controlled substance and set up a satellite pharmacy.
2. Acquiring Controlled Substances	✍ Acquire controlled substances applying one of the following subprocesses: ✍ Procuring Controlled Substances Through the CRC Pharmacy ✍ Transferring Controlled Substances from Outside Collaborators ✍ Transferring Controlled Substances Between Principal Investigators/Lead Experimenters at BNL ✍ Unplanned Transferring of Controlled Substances Between Principal Investigators/Lead Experimenters When the CRC Pharmacist is Unavailable
3. Storing, Dispensing, and Using Controlled Substances	✍ Notify CRC Pharmacist of satellite pharmacy installations. ✍ Prepare a Controlled Substance Running Inventory Log for each controlled substance. ✍ Ensure staff receives training. ✍ Maintain an accurate and complete record of usage.

	✍ Return log with empty vial or container to CRC Pharmacist. ✍ Conduct and document semi-annual inspection of inventories. ✍ Ensure CRC Pharmacy records are reviewed biennially.
4. Disposing of Controlled Substances	✍ Document unused quantity and return with log to CRC Pharmacist. ✍ Obtain DEA approval and ship material with disposal forms to disposal agency.
5. Maintaining Approved Records	✍ Retain records of dispensed substances. ✍ Maintain and annually update list of authorized staff who may use controlled substances in their work. ✍ Conduct and document semi-annual inspection of inventory. ✍ Report discrepancies to CRC Pharmacist to be recorded. ✍ Investigate discrepancies, document findings, and maintain reconciled inventory report for each satellite pharmacy. ✍ Report discrepancies to DEA and NYS Dept. of Health Bureau of Controlled Substances. ✍ Maintain a record of the lock box inventory. ✍ Maintain a record of the life cycle (cradle-to-grave) of all controlled substances.

Definitions

Exhibits
None

Forms
Controlled Substance Order Form (C-012)
Controlled Substance Report Form (C-014)
Investigator Initiated Lockbox Inspection Report (C-016)

Training Requirements and Reporting Obligations

This subject area contains training requirements. See the Training and Qualifications Web Site.

This subject area contains the following reporting obligations:

- The DEA requires that a running inventory be maintained for controlled substances. See the section Storing, Dispensing, and Using Controlled Substances for information about the Controlled Substances Running Inventory Log.
- Stolen or missing controlled substances are reported to the DEA and the New York State Department of Health Bureau of Controlled Substances.
- DEA requires that protocols which propose to use Schedule I controlled substances

- DEA requires that protocols which propose to use Schedule I controlled substances that are not on the BSA license be approved before procuring those controlled substances.

References

21 CFR 1308, Schedule of Controlled Substances

BNL Institutional Animal Care and Use Committee (IACUC)

BNL Institutional Review Board (IRB)

Integrated Assessment Subject Area

New York State Department of Health Bureau of Controlled Substances

Records Management Subject Area

Training and Qualifications Web Site

Work Planning and Control for Experiments and Operations Subject Area

Standards of Performance

All staff and guests shall comply with applicable Laboratory policies, standards, and procedures, unless a formal variance is obtained.

All staff and users shall identify, evaluate, and control hazards in order to ensure that work is conducted safely and in a manner that protects the environment and the public.

All staff and users shall ensure that they are trained and qualified to carry out their assigned responsibilities, and shall inform their supervisor if they are assigned to perform work for which they are not properly trained or qualified.

Management System

This subject area belongs to the **Work Planning and Control** management system.

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Introduction: Using Controlled Substances in Research

Effective Date: **September 2002**

Point of Contact: Clinical Research Center (CRC) Manager

This subject area describes the procedures necessary to establish and operate a controlled substance program. The Controlled Substances Act of 1970 (PL-513) assigned the Drug Enforcement Administration (DEA) the responsibility for establishing policies and procedures for the order and usage of certain drugs.

Brookhaven Science Associates (BSA) holds the only institutional DEA license that allows controlled substances to be used in research at BNL. Collaborators who transfer controlled substances to the BNL site must comply with all provisions of the BSA license. BSA must ensure that employees who handle controlled substances (i.e., those substances defined in 21 CFR 1300 – end) do so in a safe manner that is in compliance with Federal and State regulations. Failure to comply with regulations in any program at any level puts BSA's DEA license in jeopardy. Loss of this license would have devastating effects on major biomedical research programs at the Laboratory.

This subject area provides requirements for the use of controlled substances in both clinical and nonclinical settings at BNL. The procedures cover procurement, storage, use, and recordkeeping of inventories of controlled substances and their disposal. Two sources of controlled substance inventories are addressed: those procurements of controlled substances under BSA management that are dispensed by the CRC Central Pharmacy; and those inventories derived from outside collaborators. Regardless of the source of the controlled substance, approved practices must be followed to maintain and dispense these substances for clinical and nonclinical studies at BNL, and to keep appropriate records.

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Subject Area: ***Using Controlled Substances in Research***

1. Obtaining Authorization

Effective Date: **September 2002**

Point of Contact: Clinical Research Center (CRC) Manager

Applicability

This information applies to staff who acquire, manage, use, have access to or supervise the use of, or store controlled substances.

Required Procedure

Life-cycle (cradle-to-grave) management of controlled substances must be planned for and approved, including the acquisition, use, supervision, storage, and disposal of controlled substances.

Step 1	The Principal Investigator/Lead Experimenter identifies the specific controlled substance (including the quantity needed for the extent of the approved work), and ensures that adequate security measures are in place when it is dispensed from the pharmacy (see the section Storing, Dispensing, and Using Controlled Substances).
Step 2	The Principal Investigator/Lead Experimenter consults with the CRC Pharmacist to determine if the controlled substance is a Schedule I substance or Schedule II - V substance (see 21 CFR 1308, Schedule of Controlled Substances).
Step 3	The CRC Pharmacist reviews the use of the controlled substance, and verifies and documents that the controlled substance is on the DEA license by checking the IRB, IACUC, or ESR applications. This may be done via e-mail notification between the CRC Pharmacist and the IRB, IACUC, or ESR. **Note:** If the new controlled substance is a Schedule I substance and is not covered on the Schedule I license, the Principal Investigator/Lead Experimenter submits the protocol to the DEA through the CRC Pharmacist.

Step 4	The Department Chair or their designee approves the use of the controlled substance (including type, quantity, and justification for use) through one of the following mechanisms: ✍ BNL Institutional Review Board (IRB) application ✍ BNL Institutional Animal Care and Use Committee (IACUC) application. ✍ Work Planning and Control for Experiments and Operations Subject Area
Step 5	Once the ESR is approved by the Department Chair, or the protocol approved by the IACUC or IRB, the Principal Investigator/Lead Experimenter contacts the CRC Pharmacist and follows the steps for setting up a satellite pharmacy and acquiring the controlled substance (see the section Storing, Dispensing, and Using Controlled Substances).

References

21 CFR 1308, Schedule of Controlled Substances

BNL Institutional Animal Care and Use Committee (IACUC)

BNL Institutional Review Board (IRB)

Training and Qualifications Web Site

Work Planning and Control for Experiments and Operations Subject Area

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Subject Area: ***Using Controlled Substances in Research***

2. Acquiring Controlled Substances

Effective Date: **September 2002**
Point of Contact: Clinical Research Center (CRC) Manager

Applicability

This information applies to staff who acquire, store, transfer, and use controlled substances.

Required Procedure

Acquiring Controlled Substances contains four subsections:

2.1 Procuring Controlled Substances Through the CRC Pharmacy

Step 1	The Principal Investigator/Lead Experimenter procures controlled substances through the CRC Pharmacy using the Controlled Substance Order Form (C-012). **Note:** Only authorized Principal Investigators/Lead Experimenters (with approval from the Department Chair via an Experimental Safety Review [see Work Planning and Control for Experiments and Operations Subject Area], BNL Institutional Review Board [IRB] protocol or the BNL Institutional Animal Care and Use Committee [IACUC] protocol) can order controlled substances.
Step 2	The Principal Investigator/Lead Experimenter ensures that all requests for controlled substances are needed for the work, that the quantity ordered is consistent with the extent of the planned work, and that adequate security measures are taken to ensure proper control once the substance is dispensed

	to them.
Step 3	Go to the section Storing, Dispensing, and Using Controlled Substances.

2.2 Transferring Controlled Substances from Outside Collaborators

Step 1	The collaborator submits a Procurement of Controlled Substances from Outside Collaborators Form (C-015) to the CRC Pharmacist for transferring a controlled substance to the BNL site.
Step 2	The CRC Pharmacist and the CRC Manager approve the request based on satisfactory completion of the following information: ✍ The controlled substance is included on the BSA DEA license; ✍ Documentation is provided indicating the amount of the controlled substance to be transferred to the BNL site, and where it will be secured; ✍ The name of the BNL Principal Investigator/Lead Experimenter.
Step 3	The CRC Pharmacist dispenses the controlled substance transferred from the outside collaborator. Go to the section Storing, Dispensing, and Using Controlled Substances.
Step 4	Upon completion of the research, return the remaining material to the CRC Pharmacy for reconciliation, including transfer and/or disposal. Go to the section Disposing of Controlled Substances.

2.3 Transferring Controlled Substances Between Principal Investigators/Lead Experimenters at BNL

Transfers of controlled substances between Principal Investigators/Lead Experimenters are allowed, but not encouraged. Both the borrowing and lending investigators must be approved procurers of controlled substances.

Step 1	The Principal Investigators/Lead Experimenters involved in the transfer notify the CRC Pharmacist of the nature of the transfer including the type, quantity, and location. If the CRC Pharmacist is not available, go to the subsection Unplanned Transferring of Controlled Substances Between Principal Investigators/Lead Experimenters at BNL When the CRC Pharmacist is Unavailable.
Step 2	The lending investigator transfers the controlled substance to the CRC Pharmacy. The CRC Pharmacist will ask the lending investigator to log out the controlled substance from their Controlled Substance Running Inventory Log and write in the name of the borrowing investigator, the quantity of the controlled substance being transferred, and the location of its storage

	controlled substance being transferred, and the location of its storage.
Step 3	The CRC Pharmacist dispenses the controlled substance to the borrowing investigator with a new Controlled Substance Running Inventory Log and a new control number for the controlled substance.
Step 4	The borrowing investigator logs the controlled substance in their lockbox and keeps track of its use on the Controlled Substance Running Inventory Log.

2.4 Unplanned Transferring of Controlled Substances Between Principal Investigators/Lead Experimenters at BNL When the CRC Pharmacist is Unavailable

Unplanned transfers of controlled substances between Principal Investigators/Lead Experimenters are allowed, but not encouraged when the CRC Pharmacist is unavailable. Both the borrowing and lending investigators must be approved procurers of controlled substances.

Step 1	The lending investigator logs out the controlled substance from their Controlled Substance Running Inventory Log and writes in the name of the borrowing investigator, the quantity of the controlled substance being transferred, and the location of its storage. Do not transfer partial quantities. **Note:** The lending investigator makes a copy of the Controlled Substances Running Inventory Log and immediately sends it to the CRC Pharmacy.
Step 2	The borrowing investigator logs the controlled substance into their lock box and safeguards the transferred original Controlled Substance Running Inventory Log (usually by keeping it in the lockbox with the substance). The borrowing investigator fills out a new Controlled Substance Running Inventory Log for the controlled substance being borrowed. The borrowing investigator makes a copy of the original log and sends it to the CRC Pharmacy. **Note:** It is the responsibility of the borrowing investigator to verify the amount of controlled substance received.
Step 3	The CRC Pharmacist contacts the borrowing investigator and fills in a new control number on the new Controlled Substance Running Inventory Log for the transferred controlled substance and receives the original Controlled Substance Running Inventory Log in return.
Step 4	The CRC Pharmacist reports all unplanned transfers to the CRC Manager.

References

BNL Institutional Animal Care and Use Committee (IACUC)

BNL Institutional Review Board (IRB)

Work Planning and Control for Experiments and Operations Subject Area

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Subject Area: ***Using Controlled Substances in Research***

3. Storing, Dispensing, and Using Controlled Substances

Effective Date: **September 2002**

Point of Contact: Clinical Research Center (CRC) Manager

Applicability

This information applies to all staff who are authorized to dispense, use, and store controlled substances.

Required Procedure

When not under the direct control of an authorized staff member, controlled substances must be secured in a locked safe, storage cabinet, or refrigerator in an approved satellite pharmacy. A refrigerator used to store controlled substances or other pharmaceuticals requiring refrigerated storage must be equipped with a thermometer able to indicate a storage temperature of 2° to 8°C or 36° to 46°F. Controlled substances are never left unattended and out of secured storage.

The steps below provide the storage requirements for controlled substances.

Step 1	The Principal Investigator/Lead Experimenter notifies the CRC Pharmacist of the installation of any satellite pharmacy. **Note:** The CRC Pharmacist maintains a list of satellite pharmacy locations.
Step 2	The Principal Investigator/Lead Experimenter establishes an approved satellite pharmacy by installing an approved lockable storage device. It must either be a permanently affixed double-locked box or a single-locked box that is located within a locked refrigerator in a lockable room.
Step 3	The Principal Investigator/Lead Experimenter secures the keys to the locks by placing them in a locked drawer, or lockable office. **Note:** Duplicate keys must be made available to the CRC Pharmacist, so they

	can be secured in the CRC Pharmacy vault.
Step 4	The CRC Pharmacist prepares a Controlled Substance Running Inventory Log to accompany each quantity of a controlled substance issued. The log has a dispensing number on it.
Step 5	The Principal Investigator/Lead Experimenter ensures that all staff with access to controlled substances receive training before they begin work. For more information, contact your Department/Division Training Coordinator or the CRC Pharmacist.
Step 6	The Principal Investigator/Lead Experimenter issues the controlled substance to their research team in the specific quantity needed for their work.
Step 7	The authorized user to whom the controlled substance is dispensed (and whose name is on the form) is responsible for the material and maintains an accurate and complete record of the use of the substance on the Controlled Substance Running Inventory Log provided by the CRC Pharmacist.
Step 8	The staff member records each withdrawal of a controlled substance for use in a project/activity on the Controlled Substance Running Log. Depending on the activity (animal work, clinical, benchtop research), the entry includes the following information: - Date; - Signature of authorized user; - Quantity used; - Remaining balance. **Note:** The authorized user may allow other trained members of the research team to use the material in performing project work, but the authorized user maintains responsibility for the physical control, inventory, and validity of use.
Step 9	When the bottle is empty, the staff member "zeroes out" the Controlled Substance Running Inventory Log, and returns the log with the empty vial or container to the CRC Pharmacist.
Step 10	Go to the section Disposing of Controlled Substances for instructions on the disposal of remaining material.
Step 11	The Principal Investigator/Lead Experimenter conducts and documents a semi-annual inspection of inventories, which is reviewed by the CRC Pharmacist according to the section Maintaining Approved Records.
Step 12	The Medical Department ensures that a review of the CRC Pharmacy records is conducted biennially (every two years). See the section Planning and Conducting Organizational Self-Assessment Programs in the Integrated Assessment Subject Area. This review assesses the consistency and completeness of records maintained in the CRC Pharmacy which document the life-cycle management of controlled substances from procurement through disposal.

References

References

Integrated Assessment Subject Area

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Subject Area: ***Using Controlled Substances in Research***

4. Disposing of Controlled Substances

Effective Date: **September 2002**
Point of Contact: Clinical Research Center (CRC) Manager

Applicability

This information applies to all staff members who dispose of controlled substances.

Required Procedure

An accurate record of the disposal of controlled substances must be maintained.

Step 1	The staff member documents the lost, spilled, or wasted quantity on the Controlled Substance Running Inventory Log and Controlled Substance Report Form (C-014) and returns the remaining material to the CRC Pharmacist with both forms. **Note:** Do not send unused or expired controlled substances to the Waste Management Division and do not handle used/expired **containers** of controlled substances as Regulated Medical Waste (RMW). However, sharps or vials that are contaminated with small amounts of controlled substances may be handled as RMW. **Note:** Do not send contaminated or possibly contaminated single-dose or multidose vials back to the pharmacy. Witness, document, and dispose of these items as RMW.
Step 2	The CRC Pharmacist obtains DEA approval and ships the material along with the appropriate disposal forms to a DEA-authorized disposal agency for destruction. **Note:** All packages are shipped via certified mail in accordance with DEA instructions.

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Subject Area: ***Using Controlled Substances in Research***

5. Maintaining Approved Records

Effective Date: **September 2002**
Point of Contact: Clinical Research Center (CRC) Manager

Applicability

This information applies to the Principal Investigators/Lead Experimenters who use controlled substances in their research, and the CRC Pharmacist.

Required Procedure

The Principal Investigators/Lead Experimenters and the CRC Pharmacist maintain records in sufficient detail to account for the receipt, use, and disposition of controlled substances used in research at BNL.

Step 1	The CRC Pharmacist retains the invoices and shipping receipts upon receiving the controlled substance.
Step 2	The CRC Pharmacist retains the returned original Controlled Substance Running Inventory Log and keeps a running inventory and controlled substance dispensing log as a record of dispensed substances.
Step 3	The CRC Pharmacist maintains and annually updates a list of authorized staff who may use controlled substances in their work.
Step 4	The staff member records each withdrawal of a controlled substance for use in a project on the Controlled Substance Running Inventory Log and completes the form. **Note:** The staff member assigned the material is responsible for accurate and current information on the Controlled Substance Running Inventory Log.
Step 5	The Principal Investigator/Lead Experimenter conducts and documents a semi-annual inspection of the inventory in each satellite pharmacy, which is reviewed by the CRC Pharmacist.
Step 6	The staff member promptly reports any discrepancy (i.e., controlled substances

	that are missing, stolen, or unaccounted for) to the CRC Pharmacist and records it on the Controlled Substance Report Form (C-014), Controlled Substance Running Inventory Log (C-013), and Investigator Initiated Lockbox Inspection Report (C-016).
Step 7	The CRC Pharmacist investigates the discrepancy, documents any findings, and maintains the reconciled inventory report for each satellite pharmacy.
Step 8	The CRC Pharmacist reports the discrepancies where required to the DEA and the New York State Department of Health Bureau of Controlled Substances.
Step 9	The staff member returns the completed Controlled Substance Running Inventory Log to the CRC Pharmacist after all the substance is used. If any quantity of the controlled substance remains after use that is not RMW, biologically contaminated, or possibly contaminated (e.g., used syringes or punctured vials should not be returned to the pharmacy), the staff member returns it to the CRC Pharmacist with the Controlled Substance Running Inventory Log. **Note:** Unused or altered (in solution or other preparation) substances should be retained in appropriate locked storage until disposed of as described in the section Disposing of Controlled Substances.
Step 10	The Principal Investigator/Lead Experimenter maintains a record of the lockbox inventory on a copy of the Investigator Initiated Lockbox Inspection Report (C-016). The original report is signed and submitted to the CRC Pharmacist.
Step 11	The Principal Investigator/Lead Experimenter maintains a record of the life cycle (cradle-to-grave) of all controlled substances in accordance with the Records Management Subject Area.

Guidelines

When making a correction to the Controlled Substance Running Inventory Log, the incorrect data should be crossed through with one line. The correct data should be entered and the correction initialed and dated by the staff member making the correction.

Corrections to errors or omissions may be made when a discrepancy between the form and the actual quantity is found provided that the explanation is simple, obvious, and is indicated on the form with the date and the signature of the person making the corrections.

References

New York State Department of Health Bureau of Controlled Substances

Records Management Subject Area

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Subject Area: ***Using Controlled Substances in Research***

Controlled Substance Order Form (C-012)

Effective Date: **September 2002**

Point of Contact: Clinical Research Center (CRC) Manager

The Controlled Substance Order Form (C-012) is provided as a Word or PDF file.

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The only official copy of this file is the one online in SBMS. Before using a printed copy, verify that it is the most current version by checking the document effective date on the BNL SBMS website.

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BROOKHAVEN NATIONAL LABORATORY
CONTROLLED SUBSTANCE ORDER FORM (C-012)

Issue to		**IRB #**	**IACUC #**
Drug Name:		**Strength:**	
Quantity:			
Pharmacy Dispensing Record	**Manufacturer**	**Expiration Date**	**Pharmacy Dispensing No.**
Requested by		**Date**	
Dispensed by		**Date**	
Received by		**Date**	

BROOKHAVEN NATIONAL LABORATORY
CONTROLLED SUBSTANCE ORDER FORM (C-012)

Issue to		**IRB #**	**IACUC #**
Drug Name:		**Strength:**	
Quantity:			
Pharmacy Dispensing Record	**Manufacturer**	**Expiration Date**	**Pharmacy Dispensing No.**
Requested by		**Date**	
Dispensed by		**Date**	
Received by		**Date**	

Subject Area: ***Using Controlled Substances in Research***

Controlled Substance Report Form (C-014)

Effective Date: **September 2002**

Point of Contact: Clinical Research Center (CRC) Manager

The Controlled Substance Report Form (C-014) is provided as a Word or PDF file.

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CLINICAL RESEARCH CENTER
BROOKHAVEN NATIONAL LABORATORY
UPTON, NEW YORK
CONTROLLED SUBSTANCE REPORT FORM (C-014)

Re: Pharmacy Dispensing #_____

Lockbox Location_____ Date _____

☐ WASTE ☐ BREAKAGE ☐ LOSS ☐ CONTAMINATION

Controlled Substance_____

Dosage_____

Quantity Wasted or Lost_____

Comments:

_____PI or Designee Date_____

_____Witness Date_____

_____Pharmacist Date_____

CLINICAL RESEARCH CENTER
BROOKHAVEN NATIONAL LABORATORY
UPTON, NEW YORK
CONTROLLED SUBSTANCE REPORT FORM (C-014)

Re: Pharmacy Dispensing #_____

Lockbox Location_____ Date _____

☐ WASTE ☐ BREAKAGE ☐ LOSS ☐ CONTAMINATION

Controlled Substance_____

Dosage_____

Quantity Wasted or Lost_____

Comments:

_____PI or Designee Date_____

_____Witness Date_____

_____Pharmacist Date_____

Subject Area: ***Using Controlled Substances in Research***

Investigator Initiated Lockbox Inspection Report (C-016)

Effective Date: **September 2002**

Point of Contact: Clinical Research Center (CRC) Manager

The Investigator Initiated Lockbox Inspection Report (C-016) is provided as a Word or PDF file.

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BROOKHAVEN NATIONAL LABORATORY
CRC PHARMACY

INVESTIGATOR INITIATED LOCKBOX INSPECTION REPORT (C-016)

DATE: _____ LOCATION: _____

PRINCIPAL INVESTIGATOR: _____

AUTHORIZED USERS/PROCURERS: _____

_____

_____

PROTOCOL #'S: _____ EXP. DATE: _____

PROTOCOL #'S: _____ EXP. DATE: _____

PROTOCOL #'S: _____ EXP. DATE: _____

PROTOCOL #'S: _____ EXP. DATE: _____

PROTOCOL #'S: _____ EXP. DATE: _____

PROTOCOL #'S: _____ EXP. DATE: _____

PROTOCOL #'S: _____ EXP. DATE: _____

CONTENTS OF LOCKBOX

PHARMACY CONTROL NUMBER	SUBSTANCE	BALANCE ON SHEET	VERIFIED BY	DEVIATION (YES/NO AND AMT.)	EXPIRATION DATE OF SUBSTANCE	COMMENTS

CONTENTS OF LOCKBOX

PHARMACY CONTROL NUMBER	SUBSTANCE	BALANCE ON SHEET	VERIFIED BY	DEVIATION (YES/NO AND AMT.)	EXPIRATION DATE OF SUBSTANCE	COMMENTS

COMMENTS FOR PHARMACIST: _____

_____

_____

_____

_____ _____ _____

PRINCIPAL INVESTIGATOR DATE PHARMACIST

BROOKHAVEN NATIONAL LABORATORY
CRC PHARMACY

INVESTIGATOR INITIATED LOCKBOX INSPECTION REPORT (C-016)

DATE: _____ LOCATION: _____

PRINCIPAL INVESTIGATOR: _____

AUTHORIZED USERS/PROCURERS: _____

_____

_____

PROTOCOL #'S: _____ EXP. DATE: _____

PROTOCOL #'S: _____ EXP. DATE: _____

PROTOCOL #'S: _____ EXP. DATE: _____

PROTOCOL #'S: _____ EXP. DATE: _____

PROTOCOL #'S: _____ EXP. DATE: _____

PROTOCOL #'S: _____ EXP. DATE: _____

PROTOCOL #'S: _____ EXP. DATE: _____

CONTENTS OF LOCKBOX

PHARMACY CONTROL NUMBER	SUBSTANCE	BALANCE ON SHEET	VERIFIED BY	DEVIATION (YES/NO AND AMT.)	EXPIRATION DATE OF SUBSTANCE	COMMENTS

CONTENTS OF LOCKBOX

PHARMACY CONTROL NUMBER	SUBSTANCE	BALANCE ON SHEET	VERIFIED BY	DEVIATION (YES/NO AND AMT.)	EXPIRATION DATE OF SUBSTANCE	COMMENTS

COMMENTS FOR PHARMACIST: _____

_____

_____

_____

_____ _____ _____

PRINCIPAL INVESTIGATOR DATE PHARMACIST

Definitions: Using Controlled Substances in Research

Effective Date: **September 2002**
Point of Contact: Clinical Research Center (CRC) Manager

Term	Definition
approved procurers of controlled substances	Those individuals engaged in research at BNL involving controlled substances who are approved by the PI to submit a Controlled Substance Order Form (C-012) for a controlled substance through the CRC Pharmacist. Approval consists of a written memo by the PI to the CRC Pharmacy indicating that certain individuals have authorization to place an approved order through the Pharmacy. (Approved procurers are also authorized recipients).
authorized recipients of controlled substances	Those individuals authorized by the Principal Investigator (PI) to receive (but not order) small amounts of controlled substances from the CRC Pharmacy. Authorization is made through a written memo by the PI to the CRC Pharmacist.
controlled substances	Those pharmaceuticals identified by the Drug Enforcement Agency as Schedule I through V controlled substances. Such substances are maintained in the Central Pharmacy safe when procured by the CRC Pharmacy and are dispensed only to authorized individuals.
CRC Pharmacist	The individual, licensed by the State of New York, who has been appointed by the CRC Manager to act as Pharmacist for the CRC.
Lead Experimenter (LE)	The Lead Experimenter (LE), alternately, Principal Investigator (PI), is that person who takes the responsibility for all the members of a team that carry out an experiment or experimental program at Brookhaven National Laboratory. LE/PIs may or may not be employees of BNL, but they shall be able to act as the spokesperson for their experiment for the purposes of this ES&H Standard.The LE/PI shall be generally knowledgeable about the technical details of the experiment and generally aware of the associated hazards, but the LE/PI does not hold the responsibility for identifying all of them. This responsibility resides within the Department/Division ES&H process covered by Work Planning and Control for Experiments and Operations Subject Area

	Control for Experiments and Operations Subject Area.
lock box	Approved boxes with lockable lids that can be permanently fixed to a wall or within a refrigerator providing secured storage of small quantities of pharmaceuticals.
Principal Investigator (PI)	See definition for Lead Experimenter (LE).
satellite pharmacy	A location outside the CRC Pharmacy which has met the requirements of this subject area as approved for secured storage of controlled substances.

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Using Controlled Substances in Research

Point of Contact: Clinical Research Center (CRC) Manager

Revision History of this Subject Area

Date	Description	Management System
September 2002	This subject area describes the procedures necessary to establish and operate a controlled substance program. The Controlled Substances Act of 1970 (PL-513) assigned the Drug Enforcement Administration (DEA) the responsibility for establishing policies and procedures for the order and usage of certain drugs. Brookhaven Science Associates (BSA) holds the only institutional DEA license that allows controlled substances to be used in research at BNL. This subject area provides requirements for the use of controlled substances in both clinical and nonclinical settings at BNL. The procedures cover procurement, storage, use, and recordkeeping of inventories of controlled substances and their disposal. Two sources of controlled substance inventories are addressed: those procurements of controlled substances under BSA management that are dispensed by the CRC Central Pharmacy; and those inventories derived from outside collaborators.	Work Planning and Controls

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